Antiviral Development for SARS: Some initial thoughts

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Initial steps

- Early communication: Pre-IND program
- Initial data from screening program
- What systems are available to assess potentially active compounds?
  - Would this vary for a direct antiviral vs. “immune modulator”
- Acknowledge the variable clinical presentation of the disease.

What might we know about a potential compound?

- Already approved or under development
  - Substantial pre-clinical and early clinical data may be available.
- “Brand new” compound
  - We should not underestimate issues related to manufacturing, formulation, clinical pharmacology and toxicology.
- The specifics of the clinical situation impact the information required.

How might a product be used?

The following represent potential uses of a new antiviral. Clinical (and pre-clinical) data to support these overlap yet also differ.

- Rx of established infection either as single therapy or in combination.
- Post-exposure prophylaxis
- Pre-exposure prophylaxis

Future course of SARS is uncertain

- The ability to conduct trials in patients is related to the course of the epidemic. There are obvious challenges in the design of such trials.
- Ideally we would integrate pre-clinical and clinical trial data to address different potential uses.
- Depending upon the number and nature of candidate compounds we will need to consider how to prioritize compounds for additional testing/entry into clinical trials.

Additional thoughts

- Emphasize how to further characterize a product with *in vitro* activity.
- Ensure an adequate infrastructure/plan is available for clinical trials.
- Availability can occur well prior to approval but information collection must proceed.
- Multiple regulatory tools exist to facilitate development.